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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/656,173	09/06/2000	Michael D. West	P 0275460 23523-0163	8933

909 7590 09/09/2004

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/656,173

Applicant(s)

WEST ET AL.

Examiner

Joseph T. Weitach

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73, 74 and 86-162 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73, 74 and 86-162 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application filed September 6, 2000, is a continuation in part of 09/527,026, filed March 16, 2000, which is a continuation in part of 09/520,879, filed April 5, 2000, which claims priority to provisional applications: 60/152,340, filed September 7, 1999; 60/153,233, filed September 13, 1999; 60/155,107, filed September 22, 1999; and 60/179,486, filed February 1, 2000.

Applicants' amendment filed May 26, 2004, has been received and entered. The specification has been amended. Claims 73, 74 87-125, 127, 128, 131, 132, 135, 137, 143, 145-162 have been amended. Claims 73, 74 and 86-162 are pending

Election/Restrictions

Applicant's election without traverse of Group XI, drawn to DNA derived from a human cell, filed June 28, 2002, was acknowledged. Claims 73, 74 and 86-162 are pending and currently under examination. All claims are drawn to the elected invention.

Priority

Amendment of the specification to recite benefit of provisional application 60/153,233, filed September 13, 1999 has addressed the arguments regarding priority.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1632

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 73, 74 and 86-162 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". Specifically, the limitation in independent claims reciting "comprising tandem repeat sequences that are more uniform than those present in telomeres of cells" of said non-human mammal is considered new matter.

Applicants argue that they have satisfied the written description requirement and that methods to determine what is being claimed were well known in the art at the time of filing. See Applicants amendment, pages 22-23. Applicants' arguments have been fully considered, but not found persuasive.

The basis of the rejection is a new matter rejection in that the specification does not support that which is being claimed. Examiner would not contest that methods of comparing telomeres were not known nor that telomeres are located at the end of chromosomes. What is at issue is whether the instant specification literal support for 'uniform tracts of telomeric repeats', supports the comparison to other cells or cell types. More specifically, there is no specific characterization of the length or for the location of the more uniform repeats in the chromosome in the instant specification that would support what is being claimed. As indicated previously, the working examples indicates that telomerase activity was measured, and the length

Art Unit: 1632

of the telomeres was measured by flow cytometry (page 36), however there was no specific characterization of the specific sequence or 'uniformity' of the telomeres.

In addition, it is noted that the claims have been amended to recite that specific cells are used in the methods of nuclear transfer, however Examiner can not find any specific support for a comparison of the first NT cell generated or a characterization of this NT cell that would support that the telomeres have been affected in a way to be encompassed by the instant claims. The examples provided by the present specification are after nuclear transfer and culture to obtain sufficient cells for comparison, not of the first cell generated.

As stated previously, MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure".

Art Unit: 1632

As discussed above, Applicants' assertion that methods for comparing telomere length and specific sequence were known in the prior art is not contested, but it is noted that the references cited (Allshire *et al.* Bassham *et al.* and Tamarin) and relied upon in Applicants' arguments is not cited in the instant specification nor made of record. However, since Applicants have failed to point to specific support or evidence in the instant specification for what is being claimed, the rejection is maintained for the reasons set forth above and of record.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 112, second paragraph, as being vague and unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are indefinite because the comparison of telomere length of a cell is dependent on what cells are being compared and when they are compared. For example, the claims presently recite "DNA of an isolated cell generated by nuclear transfer" however it is unclear at what time after the cell is generated that the comparison is made, and it is unclear even if the claims encompass cells from non-human animals generated from the nuclear transfer methodology. Moreover, the telomeres of cells from a non-human are subject to the specific cell picked for comparison. It is noted that not all cells of a mammal are subject to telomere variation, such as MI or MII oocytes or other stem cells present in a mammal. The metes and bounds of the claims are indefinite because the

Art Unit: 1632

claims are relative to specifically what is being compared and is subject to change based on the specific comparison.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 73, 74, 87-92, 102-109, 119-124 and 147-162 rejected under 35 U.S.C. 101

because the claimed invention is directed to non-statutory subject matter is withdrawn.

The amendment to the claims to encompass an isolated DNA has obviated the basis of the rejection.

Claims 73, 74 and 86-162 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility is withdrawn.

The utility of re-cloning indicated by Applicants as supported by the specification (page 14, lines 14-22) is noted. Examiner agrees that this could be one possible utility. Therefore, in view of the support of the specification for one utility of the claimed subject matter, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

Art Unit: 1632

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 73, 74 and 86-162 stand rejected under 35 U.S.C. 102(b) as being anticipated by Stice *et al.* (US Patent 5,945,577-issue date August 31, 1999).

Claims 73, 74 and 86-162 stand rejected under 35 U.S.C. 102(b) as being anticipated by Cibelli *et al.* (Science 280:1256-1258, May 1998).

Applicants argue that the cited reference does not teach to use the same cells for nuclear transfer, there fails to teach each of the limitations of the claimed invention because they do not teach the same methodology. See Applicants amendment, pages 21-22. Applicants arguments have been fully considered, but not found persuasive.

Initially, it is noted that a product, not a method is being claimed. As noted previously, when the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Stice *et al.* teach that CICM cells

Art Unit: 1632

produced by nuclear transfer can be used as nuclear donors (column 15, lines 44-47). The DNA used in this methodology is the chromosome present in the nucleus of a cell, therefore Stice *et al.* teach DNA that anticipates the claims.

Neither the specification nor Applicants arguments have indicated why the starting material would result in any different type of cell. More importantly, the instant specification teaches that any cell can be used to achieve the claimed product. The instant specification does not teach new methods of nuclear transfer, only a characterization of the telomerase activity after performing these art recognized methods. Again, Stice *et al.* teach a method of cloning of non-human mammals comprising the use of nuclear transfer methodology as presently disclosed.

Using donor cells from pigs and cattle the methods were reduced to practice (see example 1). As indicated in the allowed claims the methods can be used to clone a non-human mammal (claim 1 for example), and includes the production of off-spring that would contain every cell within said cloned animal (claim 7). Further, it is taught the methodology can be used to generate transgenic animals wherein heterologous nucleic acid sequences can be introduced. Because the methods taught by Stice *et al.* are the same as used in the instant specification the cells produced by the methods would be the same. In particular, carrying out the methods of nuclear transfer taught by Stice *et al.* would produce cells in which the telomeres are affected as described in the instant application. It is noted that Stice *et al.* do not specifically characterize the telomeres in the cells or animals produced, however since nuclear transfer methodology is used, the resulting cell(s) would inherently have affected telomeres. Review of specific teachings of the instant specification does not provide any specific alternative steps not generally known in the art for nuclear transfer methodology. Therefore, the teaching and practice of nuclear transfer

methodology in the prior art would result in a cell containing DNA as instantly claimed. Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). Stice *et al.* teach that CICM cells produced by nuclear transfer can be used as nuclear donors (column 15, lines 44-47). The DNA used in this methodology is the chromosome present in the nucleus of a cell, therefore Stice *et al.* teach DNA that anticipates the claims.

Similarly, Cibelli *et al.* teach a method of calves comprising the use of nuclear transfer methodology. Using the nuclear material from fetal fibroblast cells several cloned calves were produced (see figure 2). Because the methods taught by Cibelli *et al.* are the same as used in the instant specification the cells produced by the methods would be the same. In particular, carrying out the methods of nuclear transfer taught by Cibelli *et al.* would produce cells in which the telomeres are affected as described in the instant application. Cibelli *et al.* teach the isolation of genomic DNA for PCR and Southern blot analysis (see figures 3 and 4). As discussed above for Stice *et al.* it is noted that Cibelli *et al.* do not specifically characterize the telomeres in the cells or animals produced, however since nuclear transfer methodology is used, the resulting cell(s) would inherently have affected telomeres. Therefore, the teaching and

Art Unit: 1632

practice of nuclear transfer methodology in the prior art would result in a cell containing DNA as instantly claimed, and the DNA analyzed by Cibelli *et al.* anticipates the claimed DNA products.

Claims 73, 74 and 86-162 are rejected under 35 U.S.C. 102(b) as being anticipated by Applicants' newly provided reference Bodnar *et al.* (Science 1998).

Bodnar *et al.* teach that expressing telomerase in a normal diploid cell results in increased telomere length (see summary in abstract). Bodnar *et al.* teach methods of isolating DNA and the comparison of the resulting DNA among the different cells generated (figure 1, for example). Bodnar *et al.* teaches the specific sequence of telomeres (page 349) and that the resulting cells have a normal karyotype (page 351). Where, as here, the claimed and prior art products are identical or substantially identical, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972). In this case, the DNA of the cells of Bodnar *et al.* with increased telomere length as compared to the starting cells anticipate the instant claims.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

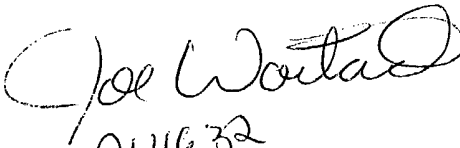
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach


AUG 32